

## **REMARKS**

### **Introductory Comments:**

Claims 1, 3, 4, 13, 16-20 and 28-50 were examined in the Office Action under reply and stand rejected solely under the judicially created doctrine of obviousness-type double patenting. This rejection is respectfully traversed as discussed more fully below.

Applicants note with appreciation the withdrawal of the previous rejections under 35 U.S.C. §112, second paragraph.

### **Overview of the Amendments:**

Claims 19, 39, 41 and 44 have been amended to insert a closing parenthesis as requested by the Office. Thus, the objection to these claims has been overcome.

### **The Double Patenting Rejection:**

All claims were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-48 and 85-112 of copending Application Serial No. 09/188,051 (“the ‘051 application”). The Examiner asserts “both sets of claims encompass a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of about 250 mg/ml and a pH about 5.5 or greater, wherein the variant has at least 80% sequence identity to human IGF-I.” Office Action, page 3. Applicants traverse this rejection.

In particular, MPEP §804(II)(B)(1) explains that the test for obviousness-type double patenting is whether the invention defined in a claim in the application is an obvious variation of the invention defined in a claim in the patent. See, e.g., *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998). However, the compositions claimed in the present application and those claimed in the ‘051 application are actually quite distinct. The most striking difference between the two compositions is demonstrated by the proposed uses as described in the respective specifications. The present application teaches a highly concentrated IGF-I formulation (see, page 4 of the present specification), whereas the teachings in the ‘051 application are directed to compositions

in which IGF-I is highly soluble at pHs of about 5.5 or greater and at refrigerated temperatures (see, page 3 of the '051 specification).

Applicants are including a claim chart in order to highlight these differences. The claim chart shows specific claim limitations present in claims 1, 34 and 42, the three independent claims in the present application, as compared to the corresponding independent claims of the '051 application. As can be seen, the concentrations of IGF-I recited in all of the independent claims of the '051 application are limited to 12-200 mg/ml whereas the corresponding concentration in the present application is 250 mg/ml or greater in independent claims 1 and 34 and 350 mg/ml in claim 42. A composition including an IGF-I concentration of 250 mg/ml in a highly concentrated form is certainly patentably distinct from a composition including IGF-I at a concentration of at most 200 mg/ml in a highly soluble form.

Additionally, each independent claim of the '051 application has a temperature limitation of 4 degrees Celsius, a limitation not found in the independent claims of the present application. Moreover, each independent claim of the '051 application requires a solubilizing compound, a limitation not found in the corresponding independent claims of the present application. Finally, claim 42 of the present application contains two additional limitations not found in the independent claims of the '051 application, namely, density and viscosity limitations. These limitations would not be obvious in light of the claims of the '051 application.

An obviousness-type double patenting rejection is improper where the claims at issue are patentably distinct from the claims in the cited patent or application. This is indeed the case in the present application. The formulations of the present application and the '051 application differ in structure and function (highly concentrated versus solubility at relatively low temperatures); the claims of the two applications include different concentration limitations and substituents (e.g., a solubilizing agent in the '051 application); and claim 42 of the present application includes a number of specific limitations absent from the '051 claims.

Based on the foregoing then, applicants submit the obviousness-type double patenting rejection cannot stand and respectfully request withdrawal of the same.

**CONCLUSION**


Applicants respectfully submit that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and an early notification to that effect would be appreciated.

Please direct all further communications in this application to:

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Respectfully submitted,

Date: 6/17/04

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## CLAIMS TABLE

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